

REMARKS

Claims 1-10, 12-14, 18-20, 22, 23, 25-29, 33, 60-63, 72, 73, 80, 86, 87, 114-116 and 127 are active.

Claims 1-3, 7-9, 13, 14, 18, 20, 23, 25, 28, 29, 33, 60-63, and 80 are rejected under 35 USC 102e as being anticipated by Anderson et al., US 6,200,347.

Claims 114-116 are rejected under 35 USC 101.

Claim 127 is objected to as the word "demineralized" is misspelled.

The restriction is made final.

The IDS cited Swedish patent is not considered.

Page 2 of the Office Action brings to the Applicants attention that copies of two Albee articles were not included with the Information Disclosure Statement. Please find enclosed the two Albee articles which were listed in the Information Disclosure Statement but were not including in the previous mailing.

The disclosure is objected to.

Objection To The Disclosure

The disclosure is objected to because of omitted data on page1 and elsewhere in the specification. The omitted data on page 1, paragraph [0002], and page 2, paragraph [0002] has been added and is shown in the appended

marked-up version of paragraph [0002].

Rejection under 35 USC 101

Claims 114-116 are rejected under 35USC101 because of the positive recitation of the "vertebral load" (claim 114, line 3) and thus the vertebrae of the patient (MPEP 2105, last paragraph). Applicants respectfully traverse the rejection. Claim 114 claims a vertebral load in relation to the fibers of the first and second cortical bone planks where the fibers are orientated in relation to the insertion direction. The insertion direction is readily defined in all spinal implants. The teeth 20, Fig. 3, bite into the vertebrae. The insertion direction is a direction to insert the tapered end 18 first in the disc space. Since such implants all have an insertion axis, such as axis 22, Fig. 2, which defines the insertion direction, the vertebral load is normal to the axis 22. Therefore the direction of the vertebral load is not defined by the person receiving the implant, but by the implant construction, as understood by one of ordinary skill. The claim states the implant has an insertion direction and that the vertebral load is normal to this direction. Therefore, the claim is not directed to a person, but to the construction of the implant, independent of the person. The vertebral load by definition is normal to the insertion direction and all spinal implants are configured to have an insertion

direction.

In addition, the rejection under 35 USC 101 is in error. This statutory section is based on statutory subject matter. Plainly, the implant as claimed is an article of manufacture under 35 USC 101 and, thus, is statutory.

The bone planks each have fibers orientated in a direction parallel to the vertebral load. The claim is not claiming the vertebrae of a patient and thereby claiming a person. The claim is orientating the bone fibers in relation to the vertebral load as defined by the insertion direction. Applicants believe claim 114 and its dependent claims 115 and 117 are not objectionable under 35 USC 101 and this basis of the rejection should be withdrawn.

The Substantive Rejections under 102(e)

Claim 1 rejection as anticipated by Anderson et al. ('347)

Claim 1 calls for:

- a first member having first and second opposing sides and a first bore defining a central longitudinal first axis, the first bore being in communication with at least the first side;

- a second member having third and fourth opposing sides and a second bore in communication with at least the third side, the second bore defining a second central longitudinal axis, the first and second axes forming a first pair; and

- an elongated first pin located in the first and second bores for securing the first member to the second member at the interface formed by the facing first and third respective sides, the pin having a first section defining a third central longitudinal axis and a second section defining a fourth central longitudinal axis, the third and fourth axes forming a second pair;

one axis of at least one of the first and second pair of axes being offset relative to the other axis of the at least one pair of axes so as to place the pin in relative compression and tension in the first and second bores for providing a compressive load on the surface of the first and second bores to frictionally secure the members together.
(emphasis added)

The present invention as claimed in claim 1 includes one axis of at least one of the first and second pair of axes being offset relative to the other axis. The Anderson reference does not disclose this structural configuration. Further, claim 1 calls for the pin having a first section defining a third central longitudinal axis and a second section defining a fourth central longitudinal axis. Additionally, claim 1 calls for the pin to be in relative compression and tension in the first and second bores. The Anderson reference does not disclose or suggest any of these elements of the claim.

A preferred embodiment of the claimed invention is shown in Fig. 2. Two planks 30 and 32 may be identical and are bonded together at their broad surfaces (specification, page 25, paragraph [00136]). Fig. 4 shows two bores 52 and 54 formed in the composite blank formed by planks 30 and 32. In this embodiment, the bores 52 and 54 have different bore sections wherein only a portion of the sections are in communication with each other and other portions have stepped surfaces (specification, page 27, paragraph [00139]). As Fig. 4 shows, the bore 52 comprises a subset of offset bores 56 and 58 whose central

axes are offset in the longitudinal direction of the implant axis 22. Similarly, bore 54 comprises a subset of offset bores 60 and 62 whose central axes are also offset in the longitudinal direction of the implant axis 22 (specification, page 27, paragraph [00139]).

Further, the offset bores shown in Fig. 4 are adapted to receive the pins 90, shown inserted, in cross section, in Fig. 2. The bending of the pin 90 creates both latent compression and tensile forces in the pin as known from general strength of materials principles relating to bent beams.

Claim 1 calls for the pin having a first section defining a third central longitudinal axis and a second section defining a fourth central longitudinal axis. An embodiment showing the different longitudinal axes is shown in Fig. 4. Bore 60 has an axis 66 and bore 62 has an axis 68 with the axes offset from each other by distance 64. If the pin 90 is assumed to be bent in the direction of the dashed lines 106 and 108 (in Fig. 4a) for purposes of discussion, then the region of the pin to the left of the axis 94 in the figure will be in compression as shown by arrows 110. The region to the right of the axis 94 will be in tension as shown by arrows 112. The compression and tension create latent compressive and tensile potential energy resilient forces in the pin and also place the pin in shear. These forces act in a direction to straighten the pin to its original configuration as shown in Figs. 4, 4a and 17.

In an alternative embodiment shown in Fig. 5, an alternative implant 198 comprises planks 200 and 202 formed as described in connection with implant 10. The difference is that bores 204 and 206 are curved with radius rather than linear. The curves of the two bores emanate from radii extending in opposite directions. The curvature of the bores is exaggerated for illustration and may be represented by straight bores inclined relative to each other in mirror image angles relative to the interface of the two planks 200 and 202.

A straight pin, such as right circular cylindrical pin 90, Fig. 17, is inserted into each the bores 204 and 206 which also are circular in cross section. The pins 90 when inserted into the bores 204 and 206 become bent. When bent they exhibit tension and compression as discussed above. The tensile and compressive beam loads form compression loads on the planks and frictionally hold the planks together. These loads are similar to the loads discussed in connection with pin 90, Figs. 4 and 4a.

In the offset pin arrangement, the compression loads induced on the adjacent implant surfaces is utilized to create static friction forces (specification, page 32, paragraph [00151]). In Fig. 2, pin 90 generates a compressive force component in direction 114 in plank 30 and an equal compressive force component in direction 116 in plank 32, which forces are components of the latent compressive and tensile bending forces of the pin in the direction of the plane of the plank normal

to the pin axis. These forces lock the planks 30 and 32 in their abutting relation precluding their separation (specification, page 34, paragraph [00156]).

The Anderson reference does not disclose the claimed pin having first and second sections relating to third and fourth central longitudinal axes, as discussed above. All the pins shown in the Anderson reference are linear with one central longitudinal axis.

Anderson discloses linear cortical pins 7 which fit into through holes 5 as shown in Fig. 11B. As shown in Fig. 15, the drill press 72 is also shown as straight. None of the through holes 5, for example, shown in Figs. 1, 9, 11B, or 12 or in any of the other embodiments show anything other than a linear hole, and the mating pins are also linear fit into the linear hole.

The Office Action points to column 28, lines 59-62 of the Anderson disclosure, which states that a compression fit is attained where the pin is configured to allow compression upon insertion where the pin expands after insertion which is achieved for example by providing the pin with a slot. Col. 28, lines 52-54, state that a connection includes, for example, an interference or friction connection where the diameter of the pin is the same as or slightly larger than the diameter of the corresponding through-hole.

As discussed above, the Anderson reference does not show or disclose offset bores as claimed in claim 1 placing the pin in relative compression and

tension in the first and second bores. The Office Action concludes that the outer surfaces of the (expanded) portions are inherently under tension. This conclusion assumes that expansion of the pin inherently produces tension. Applicants believe this conclusion to be in error, and request that references be provided which teach this inherent tension. In lieu of references, the Examiner is respectfully requested to supply an affidavit as to his personal knowledge as required by 37 CFR 1.104(d), as to the expanded portions being inherently under tension. Further, the Office Action concludes that the inner surfaces of the portions, along with the rest of the pin, are under compression. The Anderson reference only refers to a compression fit (Anderson, page 28, line 59) of the pin where the pin is configured to allow compression upon insertion where the pin expands after insertion (page 28, lines 59-61). As stated above, the bending of the pin as claimed in claim 1 creates both latent compression and tensile forces in the pin as known from general strength of materials principles relating to bent beams. Thus, the claimed invention is not disclosed by the Anderson reference, and claim 1 is believed allowable.

Dependent claims 2,3,7-9,13,14,18,20,23,25,28,29,33.

The above claims are also rejected under 35 USC 102e as being anticipated by Anderson. The dependent claims above are dependent on claim 1 and thereby

incorporate all of the subject matter claimed in claim 1 and are not anticipated by Anderson for at least the same reasons, and for the additional subject matter claimed, and are thus believed allowable over Anderson.

Independent claim 60

Independent claim 60 includes a means plus function clause.

means for placing the pin in both compression and tension to frictionally hold the pin to the members and the members together.

The fact that the claims are couched in means plus function terminology places them within the purview of 35 USC 112, 6th paragraph. Section 112 paragraph 6 defines how a claim is to be construed. Means plus function is to be evaluated in terms of the specification and equivalents thereto. Further, the MPEP 2181 discusses In re Donaldson as to how to interpret 35 USC 112, 6th paragraph claims.

35 U.S.C. §112, ¶6, reads as follows:

"element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof."

MPEP 2181 states that a claim limitation is interpreted to invoke 35 USC 112, sixth paragraph if it meets the following 3-prong analysis:

- A) the claim limitations must use the phrase “means for” or “step for”;
- B) the “means for” or “step for” must be modified by functional language;
and
- C) the phrase “means for” or “step for” must not be modified by sufficient structure, material or acts for achieving the specified function.

The relevant clause of claim 60 uses the phrase “means for”. The phrase is modified by the functional language “placing the pin in both compression and tension”. Further, there is insufficient structure, material or acts to achieve the specified function. That is, there is no structure recited for placing the pin in both compression and tension. Thus, 35 USC 112, sixth paragraph is properly invoked for claim 60.

If a portion of the claim is construed to be one that is covered by 35 U.S.C. §112 ¶6, then that portion of the claim must be interpreted under the provisions of 35 U.S.C. §112 ¶6.

If a claim is to be construed under 35 U.S.C. §112, ¶6, the examiner must determine, as a matter of law, whether and what structure described in the specification performs a function identical to that performed by the claimed function. MAS Hamilton Group v. LeGard, Inc., 156 F.3d 1206, 1211 (Fed. Cir.

1998).

Once the structure that performs the function is identified in the patent specification, the accused device is compared to such function and structure, and a determination is made, as a question of fact as to whether or not the accused device performs the identical function and whether the accused device includes equivalent structure. Id. at 1211-1212. (Emphasis added). This deals with infringement, but the principles apply equally if the accused device is deemed to correspond to a reference. It is well settled that which infringes if later, anticipates if earlier.

The function claimed is placing the pin in both compression and tension. The corresponding structure to perform the claimed function is shown in the embodiments and was discussed above by way of example for the subject matter of claim 1. These embodiments are believed providing corresponding structure that one skilled in the art would understand as performing the claimed function.

Once the structure that performs the function is identified in the specification, the reference is compared to such structure, and a determination is made, as a question of fact as to whether or not the reference, structure performs the identical function. MAS Hamilton Group v. LeGard, Inc., at 1211-1212. (Emphasis added). It is believed plain that the Anderson reference does not disclose structure that performs the identical function. Anderson is missing the

offset bores 56 and 58 of bore 52 for example, as discussed in regard to claim 1. The linear pins and mating linear bores of Anderson do not perform the claimed function of placing the pin in both compression and tension. Thus, the Anderson reference does not disclose an identical function to the claimed function and, thus, Anderson can not disclose an equivalent structure.

As the MPEP states §2184, page 2100-181, right hand column, discussing factors to be considered in deciding equivalence,

"unless an element performs the identical function specified in the claim, it cannot be an equivalent for the purpose of 35 USC 112, sixth paragraph" citing *Pennwalt Corp.*

Thus, Applicants believe claim 60 to be allowable.

Dependent claim 61.

Claim 61 is also rejected under 35 USC 102e as being anticipated by Anderson. Claim 61 is dependent on claim 60 and thereby incorporates all of the subject matter claimed in claim 60 and is not anticipated by Anderson for at least the same reasons, and for the additional subject matter claimed, and is thus believed allowable.

Independent claim 62

Independent claim 62 is also rejected under 35 USC 102e as being anticipated by Anderson. Claim 62 includes the pin and bores being arranged to place the pin in both compression and tension. As discussed above, Anderson does not disclose or suggest this and this claim is believed allowable over the Anderson reference.

The Substantive Rejections under 103(a)

Claims 4-6, 10, 12, 19, 22, 26, 27, 72, 73, 86, 87, 114-116 and 127 are rejected under 103(a).

Applicants believe the dependent claims 4-6, 10, 12, 19, 22, 26 and 27 to be novel as dependent from allowable base claim 1 which is not anticipated by the Anderson reference as discussed above. Applicants also believe the above dependent claims, as well as base claim 1, to be unobvious over the Anderson reference.

A *prima facie* case for obviousness in view of the Anderson reference has not been established with respect to claim 1. To establish a *prima facie* case for obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art (MPEP 2143.03). MPEP 2143.01 states that the fact that

references can be combined or modified is not sufficient to establish prima facie obviousness, and the fact that the claimed invention is within the capabilities of one of ordinary skill in the art is not sufficient by itself to establish prima facie obviousness. The MPEP states that the prior art need also suggest the desirability of the modification or combination. Further, the MPEP states that it is not sufficient to establish a prima facie case of obviousness without some objective reason to combine the teachings of the references.

The Anderson reference does not teach or suggest the claimed invention as claimed in claim 1 from which certain of the above claims depend. As discussed above in regard to the 35USC102 rejection of claim 1 over Anderson, the Anderson reference does not disclose, nor does it teach or suggest offset bores as claimed in claim 1 placing the pin in relative compression and tension in the first and second bores.

In the specification (page 26, paragraph [00137]) of the present invention, the disadvantage of the prior art interference fit of pins is discussed and the present invention provides a solution to these shortcomings. One disadvantage includes that when the implant is dried, the hole size relative to the pin may lead to splitting of the bone planks as shown in Figs. 80 and 82. The present invention provides a solution to the prior art problems by using offset bores as claimed in claim 1 and described by way of example in the specification page 27, paragraph

[00139].

The Anderson reference teaches an interference or friction connection ('347 col. 28, lines 52-54; col. 17, lines 55-63). This teaches away from the claimed invention. Thus, there is no motivation or advantage for one skilled in the art to modify Anderson to arrive at the present invention. Since Anderson neither teaches nor suggest the claimed invention, claim 1 is believed allowable and the dependent claims above are also believed to be unobvious over the Anderson reference as being dependent on allowable claim 1 and for additional subject matter claimed.

Claim 72

Claim 72 calls for a first planar member and a second L-shaped member with the first member disposed in a recess form by the second member. The Office Action states that the L-shaped second member (also claimed in claim 10) would have been obvious in order to simplify the process of forming the interlocking means described at column 14, lines 2-20 of Anderson. Applicants disagree that this reference discloses or suggests what is claimed. Anderson does not disclose or suggest the claimed L-shaped second member and the first member, nor provide motivation for modifying Anderson to arrive at the claimed L-shaped member and the first member. The conclusion in using generalities to

reconstruct the specific claimed invention using the applicant's disclosure (MPEP 2145 is improper. No convincing line of reasoning is provided to support the conclusion. Claim 72 is believed allowable.

Claims 87, and 114

The Office Action states that the claimed fiber direction would be obvious. Applicants disagree. The Anderson reference does not teach or suggest the claimed fiber direction in claim 87 and fiber orientation in claim 114. The conclusion in using impermissible hindsight to reconstruct the claimed invention using the Applicant's disclosure (MPEP2145). Specific prior art references are respectfully requested which disclose the claimed fiber direction, or an affidavit under 37 CFR 1.104(d) is respectfully requested as to personal knowledge pertaining to the claimed fiber direction. Claims 87 and 114 are believed allowable.

Claim 127

Claim 127 claims the bone having fibers running generally in a direction parallel to the broad surfaces of each plank, and the bore having a longitudinal axis that is normal to the fiber direction. Applicants disagree that claim 127 is obvious over Anderson. The Anderson reference does not teach or suggest the

claimed fiber direction as discussed with regard to claim 114 above. The conclusion uses impermissible hindsight to reconstruct the claimed invention using the applicant's disclosure. The Anderson reference does not teach or suggest the claimed fiber direction.

The Office Action also states that claim 127 is obvious in view of Anderson and points to column 19, lines 22-29; column 28, lines 13-14; and column 29, line 21. Column 19 refers to demineralization, column 28 refers to chemical connectors and known methods of biochemical surface modification, and column 29 refers to modifying the surface of the mechanical connector.

Claim 127 calls for forming crystals on the demineralized surface of each plank, and interlocking the formed crystals of each bone. Anderson does not disclose forming crystals and interlocking the formed crystals on each bone. Neither of these elements of the claim are taught or suggested by Anderson, nor is any motivation found in Anderson to arrive at the claimed invention.

Thus, claim 127 is believed allowable.

For the reasons given, claims 1-6, 7-9, 10, 12, 13, 14, 18, 19, 20, 22, 23, 25, 26, 27, 28, 29, 33, 60-63, 72, 73, 80, 86, 87, 114-116, and 127 are believed to be in condition for allowance, and such favorable action is hereby solicited.

No fee is believed due for this paper.

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